Food and Drug Administration, HHS

§ 520.1448 Monensin oral dosage forms.

Monensin, as the base or the sodium salt, contains a minimum of 90 percent monensin activity derived from monensin A and a minimum of 95 percent derived from monensin A plus B. Using thin layer chromatography, the R_f value must be comparable to a reference standard (the R_f value is the distance the spots travel from the starting line divided by the distance the solvent front travels from the starting line). The loss on drying is not more than 10 percent when dried in vacuum at 60 °C for 2 hours.

[55 FR 3586, Feb. 2, 1990]

§520.1448a Monensin blocks.

- (a)(1) Specifications. Each pound of protein-mineral block contains 400 milligrams of monensin (0.088 percent) as monensin sodium.
- (2) Sponsor. See 067949 in §510.600(c) of this chapter.
- (3) $Related\ tolerances.$ See §556.420 of this chapter.
- (4) Conditions of use—(i) Amount. 80 to 200 milligrams of monensin (0.2 to 0.5 pound of block) per head per day.
- (ii) *Indications for use*. Increased rate of weight gain.
- (iii) Limitations. Block to be fed free choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). Provide at least 1 block per 5 head of cattle. Feed blocks continuously. Do not feed salt or minerals containing salt. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal). The effectiveness of this block in cull cows and bulls has not been established.
 - (b) [Reserved]
- (c)(1) Specifications. Each pound of protein block contains 175 milligrams of monensin (0.038 percent) as monensin sodium.
- (2) *Sponsor*. See No. 066071 in §510.600(c) of this chapter.
- (3) Related tolerances. See §556.420 of this chapter.
- (4) Conditions of use—(i) Amount. 40 to 200 milligrams of monensin (0.25 to 1.13 pounds or 4 to 18 ounces of block) per head per day.

- (ii) *Indications for use*. Increased rate of weight gain.
- (iii) Limitations. Blocks to be fed free choice to pasture cattle (slaughter, stocker, and feeder). Provide at least 1 block per 4 head of cattle. Do not allow cattle access to salt or mineral while being fed this product. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal). Block's effectiveness in cull cows and bulls has not been established.
- (d)(1) Specifications. Each pound of block contains 400 milligrams of monensin (0.088 percent) as monensin sodium.
- (2) Sponsor. See 051267 in \$510.600(c) of this chapter.
- (3) Related tolerances. See §556.420 of this chapter.
- (4) Conditions of use—(i) Amount. 50 to 200 milligrams of monensin (2 to 8 ounces of block) per head per day.
- (ii) *Indications for use*. Pasture cattle: Increased rate of weight gain.
- (iii) Limitations. Blocks to be fed free choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). Provide at least one block per five head of cattle. Feed blocks continously. Do not feed salt or mineral supplements in addition to the blocks. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal). The effectiveness of this block in cull cows and bulls has not been established.

[46 FR 19466, Mar. 31, 1981]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §520.1448a, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsus.gov.

§ 520.1450 Morantel tartrate oral dosage forms.

§520.1450a Morantel tartrate bolus.

(a) Specifications. Each bolus contains 2.2 grams morantel tartrate equivalent to 1.3 grams of morantel base.